UNITED STATES DISTRICT COURT FOR THE
DISTRICT OF MASSACHUSETTS

UNITED STATES OF AMERICA ex rel. SUSAN HUTCHESON and PHILIP BROWN, Plaintiffs, v. BLACKSTONE MEDICAL, INC., Defendant.	Civil Action No. 1:06-cv-11771-WGY

BLACKSTONE MEDICAL, INC.'S RESPONSE TO UNITED STATES' STATEMENT OF INTEREST REGARDING DEFENDANT'S MOTION TO DISMISS

INTRODUCTION

On November 6, 2008, the United States District Court for the Eastern District of Arkansas rejected virtually every argument the government has raised, once again, in the Statement of Interest ("SOI") it filed in this Court. *See U.S. ex rel. Thomas v. Bailey*, No. 4:06CV00465-JLH, 2008 WL 4853630 (E.D. Ark. Nov. 6, 2008); *Thomas*, United States' Am. Statement of Interest on Defs.' Mot. to Dismiss, D.E. 207 (July 9, 2008) ("*Thomas* SOI") (attached as Exhibit A hereto). In *Thomas*, in its briefing and oral argument, the government asserted that claims hospitals submitted to Medicare violated the False Claims Act, 31 U.S.C. § 3729 ("FCA"), if, as the relator alleged, the services covered by the claim included procedures performed by physicians who (a) ordered Blackstone products for use during the procedures and (b) were paid kickbacks by Blackstone. Judge Holmes disagreed.

The *Thomas* and *Hutcheson qui tams* are so closely related that the government's SOI is nothing more than a collateral attack on Judge Holmes's decision in litigation involving the same legal dispute between the United States and Blackstone. But for some additional, disparaging

comments about the *Thomas* decision, the SOI the government filed in this Court is substantively identical to the one it filed in *Thomas*. Notably, when it filed the *Thomas* SOI, the government was well-aware of the overlapping allegations Relator Hutcheson had raised against Blackstone in this Court. In fact, by then, the government identified that overlap to this Court when it sought to lift the seal on this matter so as to advise Relator Thomas that this case was pending. *See* Mot. for Partial Lifting of Seal, D.E. 9 (Apr. 23, 2007). Later, in *Thomas*, the government cautioned Judge Holmes that his decision could have implications for other enforcement actions. *See Thomas* SOI at 2. This is the one action in which the implications of the *Thomas* decision are most clear. Whether this Court relies on the law of the case doctrine, the first-to-file bar, or the government's own admissions, the decision in *Thomas* governs the continuing dispute between Blackstone and the United States, regardless of which surrogate or U.S. Attorney's Office makes the argument.

Under the FCA's *qui tam* provisions, the government has several means to protect the integrity of a pending investigation and control civil litigation itself. It can intervene in the matter; it can move to dismiss a relator whose strategy imperils its strategy in another matter or investigation; and it can have cases transferred. *See* 31 U.S.C. § 3130 (2009). Or—as it did here—the government can gamble. The government can try to secure a win in one declined *qui tam* while investigating the same conduct in connection with another. Here, the government gambled, and lost. Its efforts to circumvent Judge Holmes's decision in *Thomas* should be rejected.

ARGUMENT

I. The Government, Like Relators, Seeks an Unprecedented Expansion of the FCA.

The SOI purports to address three discrete legal issues raised by Blackstone's motion to

dismiss: (1) how the "cause to be presented" theory of FCA liability works; (2) how express certification claims work; and (3) how Rule 9(b)'s heightened pleading standard applies to claims under the FCA. As they did in *Thomas*, the government's arguments miss the point, taking aim at a straw man of the government's creation. It is neither Judge Holmes's decision in *Thomas* nor Blackstone's argument here that "conflates" elements of an FCA violation so as to disregard words in the statute; it is the government's argument that emphasizes one element and ignores another. (*See* SOI at 9.) The government's entire theory of liability turns on the notion that a bad act that plays any role in causing a claim to be submitted to Medicare also "taints" that claim, even though the word "taint" appears nowhere in the Act, such that its submission violates the *False* Claims Act, regardless of the content of the claim or the applicable reimbursement model. (*See id.* at 11-12.)

The issue in this case is whether the FCA provides the government an additional remedy for *all* violations of the Anti-Kickback Statute ("AKS"), 42 U.S.C. § 1320a-7b, regardless of their relationship to a particular claim. Title 42 of the U.S. Code authorizes the government (but not private citizens) to pursue criminal and/or administrative penalties against persons who knowingly and willfully pay remuneration to someone to induce that person to purchase or order any item for which payment may be made in whole or part under a federal health care program ("FHCP"). *Id.* §§ 1320a-7a, 1320a-7b(b). Proof that a claim was submitted to a FHCP is *not* an essential element of liability under the AKS. Proof that a claim was submitted and that the claim was *false* is, however, essential to proving liability under the FCA. Courts have repeatedly recognized that the FCA does not create liability for violations of federal law unless a false claim results from that violation. *See, e.g., U.S. ex rel. Gagne v. City of Worcester*, 565 F.3d 40, 48 (1st Cir. 2009) ("'FCA liability does not attach to violations of federal law or regulations . . .

that are independent of any false claim.'" (omission in original) (quoting *U.S. ex rel. Rost v. Pfizer, Inc.*, 507 F.3d 720, 727 (1st Cir. 2007))). As Judge Saris held in *U.S. ex rel. Franklin v. Parke-Davis*, a case mis-described in the SOI, the initial inquiry into whether the claim is false or fraudulent turns on the representations, express or implied, made in its presentation; the inquiry into whether a third-party caused that claim to be submitted is a separate inquiry that may, or may not, turn on that third-party's bad acts. *See* 147 F. Supp. 2d 39, 52 (D. Mass. 2001) (*Franklin I*) ("Thus, the alleged FCA violation arises—not from unlawful off-label marketing activity itself—but from the submission of Medicaid claims for uncovered off-label uses induced by Defendant's fraudulent conduct."); *see also U.S. ex rel. Franklin v. Parke-Davis*, No. Civ. A. 96-11651PBS, 2003 WL 22048255, at *1-5 (D. Mass. Aug. 22, 2003) (*Franklin II*).

The government asks the Court to adopt unprecedented theories of causation and implied certification as a means to establish FCA liability of a sort no court has upheld before. Contrary to the strands of argument the government attempts to weave into a fanciful tapestry by selectively excerpting decisions in other cases and contexts, no court has held that conditions of payment applicable to hospitals apply with equal force to all participants in the supply chain for items and services that arguably combine to form a hospital service delivered to treat a particular diagnosis. Unlike military or other contracts where subcontractors are bound by contract to deliver products that meet certain specifications, and whose invoices to the prime contactors expressly or impliedly represent such compliance, FHCP Diagnostic Related Group ("DRG") reimbursement does not require supplier certification or impose on hospitals a duty to ensure subcontractor compliance. The Court should decline to create liability under either theory the government suggests, especially where the government neither can nor does point to any statute, regulation, or case law that supports the position it offers here. Simply put, no allegation

plausibly demonstrates that the claims submitted by the hospital—for a pre-determined DRG reimbursement amount based on a patient's diagnosis and age and that did not seek reimbursement for any particular device—were false. And absent falsity, there can be no liability under the *False* Claims Act.

The theory the government espouses here (and espoused in *Thomas*) stretches the FCA beyond recognition—proposing either to read the requirement of a "false claim" out of the FCA entirely, or advocating that the inquiry into a claim's falsity should be utterly divorced from the contents of the payment request or the context in which it is made. Neither option is acceptable, no court has adopted either, and Judge Holmes declined to adopt either in *Thomas*. The result here should be no different.

II. The SOI Does Not and Cannot Revive the Amended Complaint; Relators Have Failed to State a Claim Upon Which Relief Can Be Granted.

A. A Hospital's Claim for the Pre-Determined DRG Payment Under the Government-Designed PPS Reimbursement Scheme Does Not Seek Reimbursement for a Specific Item (Device), Thereby Precluding FCA Liability Under the Circumstances Alleged in the Amended Complaint.

The government recognizes that the allegedly false claims in this case were claims submitted by hospitals for a pre-determined reimbursement amount that did not turn on—or even require the submitting hospital to specify—whether an implant product may have been used in treating the diagnosis. (SOI at 12 (hospitals sought "a flat amount for the disease or procedure" and "not for the particular spinal implant").) That is correct. The DRG system is "[a] classification system that groups patients according to diagnosis, type of treatment, age, and other relevant criteria. Under the prospective payment system, hospitals are paid a set fee for treating patients in a single DRG category, regardless of the actual cost of care for the individual." *What is a "DRG,"* Medicare & Medicaid Guide (CCH) ¶ 5110 (2009); *see also*

MedPac, Hospital Acute Inpatient Services Payment System 1 (Oct. 2008), http://www.medpac.gov/documents/MedPAC_Payment_Basics_08_hospital.pdf ("Medicare beneficiaries enrolled in the traditional fee-for-service program receive care in about 3,500 facilities that contract with Medicare to provide acute inpatient care and *agree to accept the program's predetermined payment rates as payment in full*. . . . The [Inpatient Prospective Payment System] payment rates are intended to cover the costs that reasonably efficient providers would incur in furnishing high quality care, thereby rewarding providers whose costs fall below the payment rates and penalizing those with costs above the payment rates."). In other words, a claim for DRG reimbursement under the Prospective Payment System ("PPS") is a claim for a set amount based on a patient's diagnosis—not on the cost, or even the delivery in most cases, of particular components of care provided to that patient to treat the specified diagnosis. The hospital is paid to deliver treatment; selecting the method and controlling the cost of that treatment is left to the hospital and the patient's physician(s).

As the *Thomas* court explained in dismissing FCA claims against Blackstone based on the same hospital DRG-reimbursed claims at issue here,

> If the patient is a beneficiary of a federal program, the hospital is not reimbursed for cervical plating devices used during surgery on an item-per-item basis. Instead, the hospital submits a Form CMS-1450 with information that describes the services provided and the patient's diagnoses, as well as other required information. Based on the information on the CMS-1450, the claim is assigned to a Diagnosis-Related Group ("DRG"), and the government then reimburses the hospital on the basis of the particular DRG.

2008 WL 4853630, at *3. The *Thomas* court recognized that under the government's payment methodology, "the hospital does not submit invoices for the products purchased for use during a surgery." *Id.* A hospital's claim for DRG reimbursement would be "legally false" if the hospital certified, in submitting the claim, that the hospital had complied with the AKS when it had not,

and the claim would be "factually false" if the claim involved an incorrect description of the patient's diagnosis or requested payment for a patient whom the hospital did not treat. *Id.* at *7. Where, as here, neither legal falsity nor factual falsity is alleged, there can be no liability under the FCA and a complaint must be dismissed. *Id.* at *7-13.

Notably, other than mentioning its disagreement with *Thomas*, the government fails to acknowledge that other courts that have addressed the DRG reimbursement scheme have observed the same reality about claims for this type of reimbursement and reached the same conclusion about FCA liability. For example, in *U.S. ex rel. Kennedy v. Aventis Pharms., Inc.*, No. 03-C-2750, 2008 WL 5211021 (N.D. Ill. Dec. 10, 2008), the relators, former Aventis sales representatives, alleged that Aventis marketed the prescription drug Lovenox for off-label uses and provided money and other things of value to induce prescriptions of Lovenox. *Id.* at *1. The court dismissed the claim, recognizing that because the alleged false claims were within the PPS/DRG reimbursement system—and thus reimbursed at a pre-determined rate based on diagnosis, rather than the particular care or services received—the complaint failed to identify any claims that were false. *Id.* at *3. The claim—and ultimate reimbursement—were for the pre-determined DRG rate, which "has nothing to do with the particular drugs prescribed or used in the patient's treatment." *Id.*

Similarly, and more recently, in *U.S. ex rel. Stephens v. Tissue Science Labs.*, No. 1:07-CV-2357-ODE, slip op. at 11-13 (N.D. Ga. Aug. 13, 2009) (attached as Exhibit B hereto), the court held that under the DRG reimbursement mechanism, whether a surgery involved the use of a non-covered surgical implant was not material to the payment of the claim submitted by the hospital to Medicare or Medicaid. Under the PPS, FCA liability could not be established because "Medicare would have paid the same DRG amount if [the implant] was used on-label,

off-label, or if an entirely different product were used." *Id.* at 13; *see also U.S. ex rel. Digiovanni v. St. Joseph's/Candler Health Sys., Inc.*, No. CV 404-190, 2008 WL 395012, at *6 (S.D. Ga. Feb. 8, 2008) (dismissing FCA action alleging that the defendant hospital submitted claims to Medicare that included impermissible charges for reusable medical equipment, and noting that "[b]ecause the PPS system pays a standard rate based on the patient diagnosis and the DRG code, the itemized charges on a patient's bill are immaterial to the amount of reimbursement a provider receives"); *U.S. ex rel. Magid v. Wilderman*, No. Civ. A.96-CV-4346, 2004 WL 945153, at *8-9 (E.D. Pa. Apr. 29, 2004) (granting summary judgment on FCA claims that the defendant hospital billed Medicare for lab tests that were not sufficiently documented to warrant reimbursement, and concluding that allegations of overcharging Medicare were unsupported because inpatient services were reimbursed on a DRG basis and laboratory services were similarly subject to a flat "facility fee" reimbursement); *U.S. ex rel. Schell v. Battle Creek Health Sys.*, No. 1:00-CV-143, 2004 WL 784978, at *4 (W.D. Mich. Feb. 25, 2004) (granting summary judgment to hospital on relator's allegation that hospital was misreporting whether a single- or multi-dose vial of anesthetic medication was administered because the hospital was reimbursed under Medicare on a flat-fee basis defined by the patient's DRG).[1]

These decisions—holding that there can be no FCA liability premised on DRG reimbursed claims that were neither legally nor factually false—make sense. Under the diagnosis-based reimbursement methodology Medicare designed to implement PPS, hospitals have an incentive to ensure that patient care is provided in a cost-efficient manner—because the

[1] The relator in *Schell* did not appeal the district court's conclusion that the hospital was entitled to summary judgment on all Medicare claims that were subject to the DRG inpatient reimbursement methodology. He did, however, appeal the district court's grant of summary judgment as to certain Medicare claims for outpatient care that were not subject to DRG reimbursement. The Sixth Circuit held that summary judgment was not warranted for those outpatient claims, which were not reimbursed on a fixed-fee basis. *See U.S. ex rel. Schell v. Battle Creek Health Sys.*, 419 F.3d 535, 538-41 (6th Cir. 2005).

hospital will be reimbursed the same amount, no matter how much the treatment regime costs the hospital to provide. This system places the burden on hospitals—not the federal government—to protect against overcharges; nothing about the identity or manufacturer of a device used in a patient's treatment is relevant to the government's payment decision. And as a result, any dispute between a supplier and the hospital about the proper charge for a given medical device is a private dispute—not one that is actionable as fraud on the government under the FCA.

Breaking new ground without admitting it, the government asserts that these basic features of DRG reimbursement do not matter in determining whether a FCA plaintiff can proceed. (*See* SOI at 12-13.) In an artfully constructed sentence, the government asserts that because compliance with the AKS is a condition of Medicare and Medicaid payment, "failure to comply renders the resulting claim false and fraudulent." (*Id.* at 13.) While that is true *sometimes*—i.e., in situations where the entity submitting the claim has violated that condition of payment and nevertheless submits a claim as if it had not—what the government leaves out is how a violation of a condition of payment by a party that does not submit a claim, and whose product has no bearing on whether the government pays the claim, renders *someone else's* claim false or fraudulent. The question in this case is *not* whether compliance with the AKS is a condition of payment; the question in this case is *whose* compliance is a condition of *the payments at issue*.

Like Relators did, the government relies on a wholly distinguishable line of cases—the "subcontractor" cases—to support its argument that violations of a condition by the producer of a component of a billed item or service render prime contractor claims false and the subcontractor liable under the FCA. But in those cases, contractor claims that made specific and material representations about the components delivered and about the performance of subcontractors had

been rendered false by subcontractor misconduct that affected the quality, quantity or description of the item or service actually delivered. Notably, the only two cases cited by the government in discussing DRG reimbursement are cases involving *factual* falsity where the government was billed for something other than that which it received. (SOI at 13 (citing *United States v. Bornstein*, 423 U.S. 303, 307 (1976), in which a subcontractor provided falsely branded electric tubes to a prime contractor and thereby caused the prime contractor to submit claims to the United States for radio kits that were factually false, and *U.S. ex rel. Roby v. Boeing Co.*, 302 F.3d 637 (6th Cir. 2002), in which claims submitted to the government were factually false because the helicopters being sold contained defective transmission gears).) As Judge Holmes recognized in *Thomas*, that line of cases is inapt precisely because the hospitals made no representations about Blackstone's products and because the performance of Blackstone's products was not affected. 2008 WL 4853630, at *11-13. Here, there is no allegation that a claim was submitted for a patient who did not have the diagnosis listed on the claim for DRG reimbursement and, notwithstanding the unfounded, generalized rhetoric in the SOI, no allegation that Blackstone caused a hospital to deliver incomplete or low-quality treatment for that diagnosis. The cases that the government ignores—*Thomas*, 2008 WL 4853630, at *11-13; *Kennedy*, 2008 WL 5211021; *Stephens*, No. 1:07-CV-2357-ODE; *Digiovanni*, 2008 WL 395012, at *6; *Magid*, 2004 WL 945153, at *8-9; and *Schell*, 2004 WL 784978—all addressed, and rejected either explicitly or implicitly, superficial reliance on the subcontractor line of cases as a basis for provider liability in a PPS/DRG reimbursement context.

B. Relators' Allegations that Blackstone Paid Kickbacks to Physicians Do Not Render a Hospital's Claim for DRG Reimbursement Legally False.

To be clear, Blackstone does not, by its argument here or in *Thomas*, seek to "insulate" those who violate the AKS from answering for their offenses. Far from it. Blackstone submits

that in the context of this case, those who commit such offenses are accountable to the government and the government has various remedies available to call them to account. The FCA is not one of those remedies, however. As Blackstone demonstrated in its reply brief in support of its motion to dismiss, the position advanced by Relators and the government here would go well beyond establishing a remedy against device manufacturers; it would result in a finding that the full amount of the DRG reimbursement paid to a hospital was "tainted" and that the *hospital* was not entitled to that payment. In those circumstances, innocent third-parties could well be called upon to refund as overpayments all funds received for prolonged, multifaceted therapies in which a Blackstone product played any part. Insulation from that result is what the law requires; it is not an escape from liability for violations of the AKS.

The government's SOI offers a tutorial on the "cause to be presented" prong of FCA liability. (*See* SOI at 5-8.) Again, the question is not whether the statute means what it says, or whether the applicable standard of causation is "but for" or "foreseeable consequence." The question is whether it applies to the circumstances alleged in this case. Assessing whether Blackstone caused false claims to be submitted by any hospital requires, first and foremost, a determination of whether the allegations show any "falsity" in the claims the hospitals submitted for DRG reimbursement.[2] Declaring those claims "tainted" by the misconduct of others–misconduct the hospital is not required to monitor or report—misses that mark.

It is beyond dispute that a false claim is the "*sine qua non*" of a suit under the FCA. *U.S.*

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[2] For example, a subcontractor could cause a contractor to submit a *factually* false claim by installing defective parts in a helicopter and invoicing the primary contractor for a compliant part. When the prime contractor then submits a claim for a functional helicopter and that helicopter is, in fact, defective, its claim would be false. A party can cause another to submit a *legally* false claim in a situation where the party submitting the claim must certify the compliance of itself and that other party with a particular statute, regulation, or requirement, and the other party misrepresents its compliance with the requirement to the claim submitter, who then passes that misrepresentation on to the government and submits a claim that is legally false.

ex rel. Karvelas v. Melrose-Wakefield Hosp., 360 F.3d 220, 225 (1st Cir. 2004) ("Evidence of an actual false claim is 'the *sine qua non* of a False Claims Act violation.'" (quoting *U.S. ex rel. Clausen v. Lab. Corp. of Am., Inc.*, 290 F.3d 1301, 1311 (11th Cir. 2002))). The insurmountable problem for Relators in this case is that, put simply, the claims the hospitals are alleged to have submitted for DRG reimbursement were not factually or legally false.

While the government incorrectly criticizes the *Thomas* decision for "conflat[ing] the FCA's distinct requirements of falsity and knowledge" (SOI at 9), the government's theory would result in the requirement of "falsity" being written out of the statute. FCA liability does not turn on the fact that a claim was submitted and that some bad act is alleged to have been committed at some point before its submission. Rather, as discussed above, FCA analysis looks at whether the claim that was actually submitted—regardless of who submitted it—was in some way legally or factually false.

Courts have held that a hospital's compliance with the AKS is a condition of payment and a potential basis of liability for the hospital under a certification theory where the hospital seeks reimbursement under a FHCP. But that context is not applicable here. The issue here is whether a hospital's claim for DRG reimbursement certifies, expressly or impliedly, anything as to the AKS compliance of *other* entities or providers who may be involved to some degree in the patient's treatment. The answer is manifestly no. When a hospital is not alleged to have any knowledge of or participation in any AKS violation, allegations that a third-party—here Blackstone—paid a kickback to a physician to induce the physician to use a Blackstone device cannot render the hospital's claim for DRG reimbursement false. Blackstone's compliance with the AKS is not a condition of participation in Medicare for hospitals, not a condition of payment for hospital claims seeking DRG reimbursement, and not material in any way to the

government's reimbursement decision.[3] The courts that have addressed DRG-based payments, including the Eastern District of Arkansas in this same dispute between the United States and Blackstone, have reached the unanimous conclusion that no FCA liability can lie in these circumstances. *See Thomas*, 2008 WL 4853630, at *7-13; *see also supra* at pp. 7-8 (discussing other cases reaching the same conclusion).

A claimant's own compliance with the AKS has been held to be a condition of payment by the government in each of the cases cited in the SOI. (*See* SOI at 3-4.) But the government is mistaken in suggesting that those cases support its newly-minted "supply chain" theory of FCA liability. Those cases stand for the proposition that a provider's act of submitting a claim for payment to a FHCP can impliedly and expressly certify that the provider has complied with the AKS.[4] The *Thomas* court recognized exactly this point: "[C]ase law supports the proposition that compliance with the [AKS] is a condition of payment under these programs, so, when a health care provider presents a claim for payment pursuant to one of those programs, *that health care provider certifies, either impliedly or expressly, that the health care provider is in compliance* with the [AKS]." 2008 WL 4853630, at *8 (emphasis added).[5]

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[3] The government's SOI provides no support for its suggestion that the hospitals where the physicians identified in the complaint performed surgery certified that the physician's selection of surgical products was in compliance with the AKS. That is because no statute or regulation requires such a certification.

[4] The string citation that the government offers to support its "supply chain" theory cobbles together selected quotations that inaccurately depict the context and holding of the several cases it cites. *See, e.g., In re Pharm. Indus. Average Wholesale Price Litig.*, 491 F. Supp. 2d 12, 18 (D. Mass. 2007) ("The government further argues that Abbott marketed the spreads of its drugs to medical providers [who in turn billed submitted claims for the drugs to Medicaid] in order to induce them to purchase its products.").

[5] Even the government has taken this position in other cases. *See, e.g.*, United States' Statement of Interest Regarding Certain Issues in DTCA's Motion for Summary Judgment at 14, *U.S. ex rel. Pogue v. Diabetes Treatment Ctrs. of Am.*, 565 F. Supp. 2d 153 (D.D.C. 2008) (No. 1: 99-cv-3298) (D.E. 181-2) (government's SOI explaining that "even in the absence of an express certification, *submission of claims from those who violate statutes* which have a direct nexus to the government's payment decision—as do the Anti-Kickback and Stark Statutes—is actionable

As a result, those cases alone do not answer the questions necessary to establish liability under the FCA here, where the claim submitter's compliance with the AKS is not in question. The government is urging the Court to apply a general rule that simply does not exist. Prior cases in which the AKS "condition of payment" construct played a role focused solely on claims for Medicare payments submitted *by the entities that were alleged to have paid the kickbacks* to obtain the right to bill—entities that the government argued were not entitled to payment because they had violated a condition of their right to request payment. *See, e.g., U.S. ex rel. McNutt v. Haleyville Med. Supplies, Inc.*, 423 F.3d 1256, 1257 (11th Cir. 2005) (holding that complaint stated FCA claim where it alleged that the defendants submitted claims for Medicare reimbursement with knowledge that they were ineligible for that reimbursement because they were paying kickbacks that violated the AKS) (cited in SOI at 4). Here, however, the billing entities are hospitals that are not alleged to have paid or received any sort of kickback. Nor does anything in Relators' allegations suggest that the hospitals could be viewed as having falsely implied their compliance with the anti-kickback condition of payment.

Under the certification theory of FCA liability, the claimant agrees to certain conditions of payment and expressly or impliedly attests that those conditions have been met. The issue here, just as in *Thomas*, is "whether the hospitals impliedly or expressly certified that [a physician's] selection of products was untainted by violations of the [AKS]." 2008 WL 4853630, at *8. While "a hospital's act of submitting a claim for payment to the government impliedly certifies that *the hospital* has complied with the [AKS]," it does not follow that "a hospital's act of submitting a claim for payment is an implied certification that a person who is not employed by the hospital, is not an agent or subcontractor of the hospital, and who does not act under the

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under the False Claims Act" (emphasis added)). Here, of course, there is no question of the "submission of claims from those who violate statutes." *Id.*

hospital's control, complied with the [AKS]." *Id.* at *9 (emphasis added).

The government cites neither regulation nor case law that imposes on hospitals any responsibility to investigate or obtain sufficient information about a physician's relationship with every third-party vendor with whom the physician interacts for the hospital to certify that the physician, like the hospital, has no relationship that runs afoul of the AKS. Nor would such a requirement be practicable given the number of physicians with surgical privileges at most hospitals. And, if the government were to impose such a requirement, it would need to do so unambiguously.[6] The government's position in its SOI tries to have the certification theory do more than it logically can by discarding the notion of certifications entirely and adopting a "taint" theory under which claims would be rendered false even if there was no legal or factual falsity to the claim submitted. That goes well beyond any theory of FCA liability that any court has ever recognized. No court has held that down-stream kickbacks "taint" claims submitted by a party that does not participate in, and has no knowledge of, a kickback scheme—especially where no claim is submitted for the item on which a kickback was allegedly paid.

The government has it exactly right when it states that the claims at issue "are not rendered false because of anything peculiar to any individual claim." (SOI at 16.) But then, in the very next sentence, the error of the government's reasoning comes through. According to the government, the claims "are false, instead because they are the result of a kickback." (*Id.*) That is incorrect. The claims at issue are not "the result of a kickback." They are a result of a

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[6] As the *Thomas* court explained, "Could the government require such a certification from hospitals as a condition of receiving payment from federal health programs? It could. But were it to do so, one would expect the language of the certification to say so unambiguously." 2008 WL 4853630, at *12. In fact, there is no question the government knows how to say so unambiguously. *Cf.* 42 C.F.R. § 411.355(f) (setting out an exception to prohibited referrals for implants at an ambulatory surgical center in the Stark Law context so long as "[t]he arrangement for the furnishing of the implant does not violate the anti-kickback statute").

diagnosis and the patient's age. Under the PPS, *see supra* at pp. 5-6, the hospital's claim is for reimbursement of the pre-determined DRG payment amount that flows from a given diagnosis for a patient of a certain age—it has nothing to do with what device is selected for use in the course of surgical treatment.

In fact, as explained in Blackstone's reply brief in support of its motion to dismiss, the Medicare program separately regulates the conduct of physicians and hospitals. Physicians and hospitals file separate enrollment forms to participate in Medicare, submit separate claims with separate certifications (CMS Form 1500 for physicians and CMS Form 1450 for hospitals), and receive separate reimbursement from separate insurance programs (Medicare Part B reimburses physicians' claims for physician services; Medicare Part A reimburses hospital claims for hospital services). *See* Reply Br. in Supp. of Mot. to Dismiss Am. Compl. at 15-16, D.E. 62 (Sept. 2, 2009). There is no legal or factual basis to find that Medicare requires hospitals to certify anything about a physician's compliance with the AKS or the relationship between an independent physician and a device manufacturer.

Just as the hospital's PPS claims for DRG reimbursement were neither legally nor factually false, neither were any hospital cost reports legally or factually false. The government makes the same express certification argument (*see* SOI at 10-11) that the *Thomas* court already

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Some of the cases cited by the government involve false claims that were submitted for off-label uses of prescription drugs. Those cases are inapposite. First, the government has failed to note that in *Franklin I*, Judge Saris held that kickbacks to induce prescriptions did not render claims submitted by pharmacists false when the kickback was allegedly paid by a manufacturer. *See Franklin I*, 147 F. Supp. 2d at 54-55; *Franklin II*, 2003 WL 22048255, at *6-7. Second, in the off-label prescription context, the claims would be legally false because they would be for non-covered uses of the drugs. *Franklin I*, 147 F. Supp. 2d at 52; *Franklin II*, 2003 WL 22048255, at *2. In this case, there is no analogous legal falsity.

properly rejected.[8] A hospital's cost report certifies its accuracy "to the best of [the certifier's] knowledge and belief"—and is therefore only a certification as to what the certifier actually knows and believes. *Thomas*, 2008 WL 4853630, at *10; Am. Compl. ¶ 62, D.E. 47 (June 4, 2009). According to the government's argument, the hospital employee signing the cost report on behalf of the hospital "would thereby certify that all of the physicians who practiced at that hospital, no matter how large the number, had complied with the laws and regulations with respect to every medical service provided in conjunction with the hospital for every patient for an entire year. It is impossible that the person signing the cost report could have that knowledge." *Thomas*, 2008 WL 4853630, at *10. The *Thomas* court also expressed incredulity at the government's argument—the same position it has taken here: "It is difficult to see why the government would require someone to certify to matters that are both beyond his knowledge and beyond what he could possibly know." *Id.* Moreover, a hospital's cost report contains a certification only as to "the services identified in this cost report." Am. Compl. ¶ 62. Importantly, physician services are *not* included in a hospital's cost report because physician services are separately billed. This further reinforces that a hospital cost report contains no certification—express or implied—as to the compliance of any physician with hospital privileges with the AKS.

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[8] *U.S. ex rel. Schmidt v. Zimmer, Inc.*, 386 F.3d 235 (3d Cir. 2004) (cited in SOI at 10), is off-base for the same reason that many of the other cases cited in the SOI are off-base. In that case, the *certifying party* was itself receiving kickbacks from the device manufacturer (Zimmer) and then "certif[ying] its compliance with federal health care law knowing that certification to be false." *Id.* at 243, 247 ("[I]t was alleged that *Zimmer and [the hospital]* induced certain of its physicians and orthopedic departments to assist in meeting Zimmer's prescribed volume and market share levels by sharing with them all or part of the rewards received from Zimmer under the contract." (emphasis added)); *see also Franklin I*, 147 F. Supp. 2d. at 54 ("In order for the antikickback violation to be transformed into an actionable FCA claim, the government must have conditioned payment of a claim upon *the claimant's* certification of compliance with the antikickback provision." (emphasis added) (citations omitted)).

II. The Amended Complaint Should Be Dismissed for Failing to Meet Rule 9(b)'s Heightened Pleading Standard.

The government, like Relators, asserts that the First Circuit's *Duxbury* decision excuses their pleading deficiencies. That assertion is flawed and unfounded. Under *Duxbury*, relators who allege a defendant caused a third party to submit false claims must provide "factual or statistical evidence to strengthen the inference of fraud *beyond possibility*." *U.S. ex rel. Duxbury v. Ortho Biotech Prods., L.P.*, No. 08-1409, __ F.3d __, 2009 WL 2450716, at *14 (1st Cir. Aug. 12, 2009) (emphasis added) (citation omitted). That decision must be read in conjunction with prior First Circuit panel decisions holding that in the FCA context, "the rule requires relators to 'provide details that identify particular false claims for payment that were submitted to the government.'" *Rost*, 507 F.3d at 731 (quoting *Karvelas*, 360 F.3d at 232).[9]

The amended complaint fails to meet the requisite standard of particularity set forth by *Karvelas*, *Rost*, and *Duxbury*. Although purporting to allege a wide-ranging scheme of kickbacks to physicians, the amended complaint never demonstrates how the alleged kickback scheme is linked to the *submission* of *false claims* by any hospital, or hospitals more generally. Without this crucial link, there is no FCA violation to pursue. *See Karvelas*, 360 F.3d at 225.

The government takes the untenable position that the only thing an FCA plaintiff needs to plead with particularity is a kickback. (*See* SOI at 15 (arguing that the who, what, where, and when of an alleged fraud can be pled simply by identifying particular doctors who allegedly received kickbacks).) That misses the point. It is the existence of false claims that must be pled with particularity. *U.S. ex rel. Poteet v. Lenke*, 604 F. Supp. 2d 313, 324 (D. Mass. 2009) ("'[T]he details of the actual presentation of false or fraudulent claims to the government can and

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[9] A later panel cannot overrule a prior panel. *See United States v. Wogan,* 938 F.2d 1446, 1449 (1st Cir. 1991) ("We have held, time and again, that in a multi-panel circuit, prior panel decisions are binding upon newly constituted panels in the absence of supervening authority sufficient to warrant disregard of established precedent.").

must be pled with particularity in order to meet the requirements of Rule 9(b).'" (quoting *Karvelas*, 360 F.3d at 228)).

Nor can the government's assertion of the sufficiency of the three redacted and incomplete lists of "claims" attached to the Amended Complaint carry the day for Relators. Nothing about this list identifies even a single claim that resulted from a kickback. To the extent the claims listed are hospital claims for DRG reimbursement, the claims did not result from a kickback; to the extent they are claims submitted by some other claimant, they are beyond the scope of the allegations in the Amended Complaint and not linked by any factual assertions to any kickback allegation.

CONCLUSION

Relators have failed to state a claim under Rule 12(b)(6) and 9(b). Nothing in the government's Statement of Interest changes that fact. As the *Thomas* court already held in dismissing essentially these same claims against this same defendant in light of the same alleged scheme, there is no plausible claim for FCA liability against Blackstone.

Respectfully submitted,

Dated: September 9, 2009

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CERTIFICATE OF SERVICE

I hereby certify that these documents filed through the ECF system will be sent electronically to the registered participants as identified on the Notice of Electronic Filing and paper copies will be sent to those indicated as non registered participants on September 9, 2009.

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